

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**Re: Appeal to the Board of Patent Appeals and Interferences**

Appellants: MacDonald et al.	)	Examiner: Nathan W. Schlientz
	)	
Serial Number: 10/731,256	)	Group Art Unit: 1616
	)	
Filed: December 9, 2003	)	Customer Number: 22827
	)	
Confirmation No: 4720	)	Deposit Account: 04-1403
	)	
Title: Triggerable Delivery System for Pharmaceutical and Nutritional Compounds and Methods of Utilizing Same	)	Attorney Docket No: KCX-859 (19100)
	)	

1. ☐ **NOTICE OF APPEAL:** Pursuant to 37 CFR 41.31, Applicant hereby appeals to the Board of Appeals and interferences from the last decision of the Examiner.
2. ☐ **PRE-APPEAL BRIEF REQUEST FOR REVIEW:** Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal. The review is requested for the reason(s) stated on the attached sheet(s) [No more than five (5) pages may be provided.]
3. ☐ **BRIEF** on appeal in this application pursuant to 37 CFR 41.37 is transmitted herewith (1 copy).
4. ☐ An **ORAL HEARING** is respectfully requested under 37 CFR 41.47 (due within two months after Examiner's Answer).
5. ☒ Reply Brief under 37 CFR 41.41(b) is transmitted herewith (1 copy).
6. ☐ "Small entity" verified statement filed: [ ] herewith [ ] previously.

7. **FEE CALCULATION:**

	<b>Fees</b>
If box 1 above is X'd enter \$ 540.00	\$ <u>0.00</u>
If box 2 above is X'd enter \$ 0.00 (no fee)	\$ <u>0.00</u>
If box 3 above is X'd enter \$ 540.00	\$ <u>0.00</u>
If box 4 above is X'd enter \$1,080.00	\$ <u>0.00</u>
If box 5 above is X-d enter \$ 0.00 (no fee)	\$ <u>0.00</u>

**PETITION** is hereby made to extend the original due date of July 12, 2009, hereby made for an extension to cover the date this response is filed for which the requisite fee is enclosed (1 month \$130; 2 months \$490; 3 months \$1,110; 4 months \$1,730, 5 months \$2,350) \$ 0.00

**SUBTOTAL:** \$ 0.00

Less any previous extension fee paid since above original due date. - \$ 0.00

Less any previous fee paid for prior Notice of Appeal since Board did not render a decision on the merits. MPEP § 1204.01 - \$ 0.00

Less any previous fee paid for submitting Brief on prior Appeal since  
Board did not render a decision on the merits. MPEP § 1204.01 - \$ 0.00

**SUBTOTAL:** \$ 0.00

If "small entity" verified statement filed ☐ previously,  
☐ herewith, enter one-half (1/2) of subtotal and subtract - \$ 0.00

**TOTAL FEE ENCLOSED:** \$ 0.00

- ☐ Fee enclosed.
- ☐ Charge fee to our Deposit Account/Order Nos. in the heading hereof (for which purpose one additional copy of this sheet is attached)
- ☒ Charge to credit card (attach Credit Card Payment Form – PTO 2038)
- ☐ Fee NOT required since paid in prior appeal in which the Board of Appeals did not render a decision on the merits.

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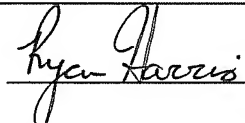
The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any fees in addition to the fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (deficiency only) now or hereafter relative to this application and the resulting official document under Rule 20, or credit any overpayment, to our Account No. shown in the heading hereof. This statement does not authorize charge of the issue fee in this case.

**DORITY & MANNING ATTORNEYS AT LAW, P.A.**

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Signature: 

Date: May 28, 2009

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I hereby certify that this correspondence and all attachments and any fee(s) are being electronically transmitted via the internet to the U.S. Patent and Trademark Office using the Electronic Patent Filing System on May 28, 2009.

Sandra S. Perkins

(Typed or printed name of person transmitting documents)

  
(Signature of person transmitting documents)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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Pharmaceutical and Nutritional	)	
Compounds and Methods of	)	Customer No: 22827
Utilizing Same	)	

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY BRIEF EXAMINER'S ANSWER**

Appellants submit the following reply brief in accordance with 37 C.F.R. § 41.41:

**1. REAL PARTY IN INTEREST**

See Appellants' Brief on Appeal.

**2. RELATED APPEALS AND INTERFERENCES**

See Appellants' Brief on Appeal.

**3. STATUS OF CLAIMS**

See Appellants' Brief on Appeal.

**4. STATUS OF AMENDMENTS**

See Appellants' Brief on Appeal.

**5. SUMMARY OF CLAIMED SUBJECT MATTER**

See Appellants' Brief on Appeal.

In addition to the claimed subject matter submitted in Appellants' Brief on Appeal, dependent claim 37 depends from independent claim 28 and adds the limitation that the vehicle is a liquid. See, e.g., pg. 2, line 25.

Dependent claim 38 depends from independent claim 28 and adds the limitation that the vehicle is a gel. See, e.g., pg. 5, line 25.

Dependent claim 40 depends from independent claim 28 and adds the limitation that the nanoparticles are located on a substrate prior to administration. See, e.g., pg. 7, line 22 – pg. 8, line 7; pg. 19, line 28 – pg. 20, line 27.

Dependent claim 44 depends from independent claim 28 and adds the limitation that the nanoparticles are topically administered. See, e.g., pg. 2, line 29.

Dependent claim 46 depends from independent claim 28 and adds the limitation that the mucosal membrane is located in a vagina. See, e.g., pg. 3, line 29 – pg. 4, line 9.

**6. GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

See Appellants' Brief on Appeal.

**7. ARGUMENT**

See Appellants' Brief on Appeal.

**Response to Examiner's Answer**

**II. Claims 28, 30, 31, 33-35, 37, 38, 40, 42-44, 46, 64 and 65 are patentable over Bosch in view of Breitbarth and Ma, as evidenced by Daraio.**

**A. Independent claim 28 is patentable over Bosch in view of Breitbarth, Ma, and Daraio.**

**1. Bosch, Breitbarth, Ma, and Daraio fail to teach or suggest nanoparticles contained within a vehicle that further comprises a pH altering material.**

In response to Appellants' arguments presented under heading II.A.1, the Examiner points to pg. 23, line 14 of Bosch that states that "for capsules, tablets, and pills, the dosage forms may also comprise buffering agents" and indicates that this disclosure anticipates the limitation on independent claim 28 that requires "wherein the nanoparticles are contained within a vehicle that further comprises a pH altering material." Appellants respectfully disagree.

Appellants teach the use of pH altering materials at pg. 16, lines 1-9 reproduced below:

Therefore, these two examples of pharmaceutical agents demonstrate the capability of selectively releasing pharmaceutical agents from the carrier particles. By the use of a "pH trigger" the functional compounds can be released in a controlled manner when needed. It should be noted that such triggering of the delivery system may be accomplished through environmental changes such as infection which results in pH changes, taking advantage of inherent differences in pH depending on body locations, and the intentional act of introducing chemistries such as pH altering materials to the delivery systems to trigger the release of functional compounds. Chemistries that may be introduced to a delivery system include bicarbonates, carbonates and buffering salts which would result in a pH change on becoming wet with water or biological fluid. In yet another example, the delivery system would be incorporated into a tampon. Normal healthy vaginal fluid is acidic, typically in the 3-5 pH range. However, when infected with a yeast infection or other microbial infection, the pH changes to the basic range. This swing in pH would trigger the release of medication or buffering agents to restore the healthy pH of the vaginal fluid and flora.

Thus, such pH altering materials are utilized in order to trigger the release of the functional compounds. In contrast, the buffering agents utilized in Bosch are utilized for capsules, tablets, and pills, presumably to achieve a pH suitable for oral administration

and to create a buffered solution that is resistant to changes in pH. Nothing in Bosch would obviate to one skilled in the art to incorporate a pH altering material into the vehicle for delivery as described and claimed by Appellants. Additionally, this disclosure in Bosch further illustrates the patentability of claims 37 (vehicle is a liquid), 38 (vehicle is a gel), 40 (nanoparticles are located on a substrate prior to administration), 44 (nanoparticles are topically administered), and 46 (mucosal membrane is located in a vagina) argued separately below.

**2. The Examiner improperly combines the teachings of Bosch with Breitbarth.**

In response to Appellants' arguments presented under heading II.A.2, the Examiner states that Breitbarth was simply relied upon for the general knowledge in the art that active agents bound to the surface of particles can be released by a change in pH. However, Appellants respectfully note that the teachings of the references must be viewed in their entirety, i.e., as a whole, to sustain a *prima facie* case of obviousness under 35 U.S.C. § 103(a). Further, the appropriate test under 35 U.S.C. § 103(a) is not whether the differences between the prior art and the claims are obvious, but instead whether the claimed invention as a whole would have been obvious. Appellants noted the stark differences between Breitbarth and Appellants claims (as well as Bosch) in order to illustrate that one skilled in the art utilizing common sense would not look to the disclosure of Breitbarth and utilize its teachings in a manner consistent with Appellants' disclosure and claims. Plainly, the Examiner's only incentive or motivation for so modifying Bosch using the teachings of Breitbarth in the manner suggested results from using Appellant's disclosure as a blueprint to reconstruct the claimed invention out of

isolated teachings in the prior art. It is improper to simply pick and choose just those components needed from a prior art reference to combine in a Section 103 combination.

The Examiner's Answer goes on to argue that Bosch discloses nanoparticles with a zeta potential of +20 mV or more. However, Appellants have not challenged this disclosure of Bosch. In the argument presented by Appellants, Appellants simply note the vast differences between the prior art as a whole and Appellants' claimed invention in illustrating that the purported combination of references is improper.

**B. Dependent claim 65 is patentable over Bosch in view of Breitbarth, Ma, and Daraio.**

In response to Appellants' arguments presented under heading II.B, the Examiner again points to Ma that indicates that the amount adsorbed onto the surface of alumina membranes is pH dependent. Furthermore, the Examiner's Answer indicates that "one of ordinary skill in the art would reasonably understand that at pH above and below 5 the amount of tetracycline that adsorbs to alumina is less than at pH 5." Again, Appellants do not dispute what the Examiner asserts.

However, what the Examiner asserts and what Ma teaches is not what Appellants disclose and claim, nor would the limitations of claim 65 be obvious from the disclosure of Ma. Ma does not teach or suggest that **after adsorption** a change in pH forces the release of tetracycline. One skilled in the art appreciates that while controlling pH may control the amount of adsorption of a compound, the reverse is not inherently and necessarily true. Ma does not teach to one skilled in the art that pH altering would necessarily force the release of the adsorbed tetracycline.

Furthermore, Appellants included additional arguments that Ma is improperly combined with the other references for reasons similar to those noted above with respect to Breitbarth and Bosch.

**III. Claims 28, 30, 31, 33-35, 37, 38, 40, 42-44, 46, 64 and 65 are patentable over Tan in view of Bosch and Breitbarth and Ma, as evidenced by Daraio.**

**A. Independent claim 28 is patentable over Tan in view of Bosch, Breitbarth, Ma, and Daraio.**

1. Contrary to that alleged in the Final Office Action, Tan fails to teach nanoparticles containing silica coated with alumina.
2. Tan, Bosch, Breitbarth, Ma, and Daraio fail to teach or suggest nanoparticles contained within a vehicle that further comprises a pH altering material.
3. The Examiner improperly combines the teachings of Bosch with Breitbarth.

**B. Dependent claim 65 is patentable over Tan in view of Bosch, Breitbarth, Ma, and Daraio.**

Regarding Appellants' arguments submitted in the above headings, the Examiner's Answer does not contain any substantial responses that haven't been addressed above or within the Appellants' Brief.

**New Arguments**

- **Claims 37, 38, 40, 44, and 46 are patentable over the cited references.**

The Examiner's Answer indicates that Appellants' claimed pH altering material is obviated by the disclosure of Bosch that a buffering agent may be incorporated into capsules, tablets, and pills for oral administration. See Bosch, pg. 23, lines 1-14. While Appellants respectfully disagree for the reasons noted above, claim 37 requires that the

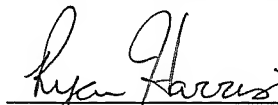


vehicle is a liquid, claim 38 requires that the vehicle is a gel, claim 40 requires that the nanoparticles are located on a substrate prior to administration, claim 44 requires that the nanoparticles are topically administered, and claim 46 requires that the mucosal membrane is located in a vagina. No proper combination of the references would disclose or suggest to one skilled in the art utilizing common sense to incorporate the disclosed and claimed pH altering material into a liquid vehicle, a gel vehicle, onto a substrate, into a product for topical administration, or for administration to a membrane within a vagina as required by claims 37, 38, 40, 44, and 46.

In conclusion, Appellants request favorable action and allowance of the presently pending claims.

Respectfully requested,

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Date: May 28, 2009

8. **CLAIMS APPENDIX**

See Appellants' Brief on Appeal.

9. **EVIDENCE APPENDIX**

None

10. **RELATED PROCEEDINGS APPENDIX**

None